



Technology Sciences Group Inc.

1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8967
Fax: (202) 872-0745
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
Senior Regulatory Consultant

September 12, 2014

**Copper Development Association, Inc.
Submission of Minor Formulation Amendment/
CSF Revision for Antimicrobial Copper Alloys
Group III, EPA Reg. No. 82012-3**

Mr. Eric Miederhoff, Acting PM-33
Antimicrobials Division **(7504P)**
Office of Pesticide Programs **(AMEND)**
U.S. Environmental Protection Agency
Document Processing Center
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

Dear Mr. Miederhoff:

Technology Sciences Group, Inc., on behalf of Copper Development Association (CDA), is submitting the enclosed minor formulation amendment with CSF revision for the above-referenced product. CDA is seeking to revise the current CSF with additional copper alloy materials. A supplemental chemistry study (Certified Limits) accompanies this formulation amendment to assist the review process. It is believed that this action be categorized as an A362 action. Please find enclosed the following documents supporting this amendment:

- 1) EPA Application for Amendment (EPA Form 8570-1) with Transmittal Document;
- 2) Certification with Respect to Citation of Data (EPA Form 8570-34);
- 3) Data Matrix, Confidential and Releasable versions (EPA Form 8570-35);
- 4) Current Confidential Statement of Formula (EPA Form 8570-4);
- 5) Proposed Revised Confidential Statement of Formula;
- 6) Supporting Reference Chemistry Data Volume – Certified Limits.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsqusa.com.

Sincerely,

Regulatory Consultant to
Copper Development Association, Inc.

Enclosures

Washington, D.C.



1150 18th St., NW, Suite 1000
Washington, D.C. 20036
Phone: (202) 223-4392

California

712 Fifth St., Suite A
Davis, CA 95616
Phone: (530) 757-1245

Canada

275 Slater St., Suite 900
Ottawa, Ontario K1P 5H9
Phone: (613) 247-6285

| | | | |
|--|---|---|---|
|  | United States Environmental Protection Agency Washington, DC 20460 | <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other | OPP Identifier Number |
| Application for Pesticide – Section I | | | |
| 1. Company/Product Number <div style="text-align: center; font-weight: bold;">82012-3</div> | | 2. EPA Product Manager <div style="text-align: center; font-weight: bold;">Eric Miederhoff</div> | |
| 4. Company/Product (Name) Antimicrobial Copper Alloys Group III | | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted | |
| 5. Name And Address Of Applicant (Include ZIP Code) Copper Development Association Inc. 260 Madison Avenue New York, NY 10016 <input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |
| Section II | | | |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <input checked="" type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below. </div> <div style="width: 48%;"> <input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain Below. </div> </div> | | | |
| Explanation: Use additional page(s) if necessary. (For section I and Section II.) Submission of Non-PRIA Fast-Track, Minor Formulation Amendment/Revised Confidential Statement of Formula for this product per PR Notice 98-10. Please confirm receipt with Micah Reynolds: mreynolds@tsqusa.com, via phone (202) 828-8967, or via fax (202) 872-0745. | | | |
| Section III | | | |
| 1. Material This Product Will Be Packaged In: | | | |
| Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container | 2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>none</u> |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | 4. Size(S) Retail Container <div style="text-align: center; font-weight: bold;">N/A – no container</div> | | 5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product |
| 6. Manner in Which Label is Affixed to Product <div style="display: flex; align-items: center;"> <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled </div> <input checked="" type="checkbox"/> Other <u>Attached to Bill of Lading</u> | | | |
| Section IV | | | |
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name Micah T. Reynolds, Technology Sciences Group, Inc. | Title Senior Regulatory Consultant | Telephone No. (Include Area Code) (202) 828-8967 | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received (Stamped) |
| 2. Signature  | | 3. Title Regulatory Consultant to Copper Development Association Inc. | |
| 4. Typed Name Micah T. Reynolds | | 5. Date September 12, 2014 | |

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter (Registrant)

EPA Company No. 82012Copper Development Association
260 Madison Avenue
New York, NY 10016Authorized Representative:Micah T. Reynolds
Technology Sciences Group, Inc.
1150 18th Street, NW, Suite 1000
Washington, DC 20036
Tel: (202) 828-8967

2. Regulatory Action for which this Package is Submitted:

Non-PRIA, Fast-Track, Minor Formulation Amendment/Revised Confidential Statement of Formula supporting the addition of copper alloys to Antimicrobial Copper Alloys Group III (EPA Reg. No. **82012-3**)

3. Transmittal Date

September 12, 2014

4. List of Submitted Documents

| MRID NUMBER | VOLUME NUMBER | EPA STUDY TITLE | GUIDELINE NUMBER |
|-----------------|------------------|---|---------------------|
| <u>49445900</u> | ADMIN | <u>Administrative Materials</u> Cover Letter; Application for Amendment; Transmittal Document; Certification with Respect to Citation of Data; Data Matrix – confidential & sanitized versions Current Confidential Statement of Formula Proposed Confidential Statement of Formula | ----- |
| <u>49445901</u> | 1 of 1 | Antimicrobial Copper Alloys Group III Supplemental Product Chemistry | 830.1750 |

5. Company Contact

Company Name: Copper Development Association Inc.

Authorized Representative:



 Micah T. Reynolds
 Regulatory Consultant
 Technology Sciences Group, Inc.
 Email: mreynolds@tsgusa.com
 Telephone: (202) 828-8967
 FAX: (202) 872-0745



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

| | |
|--|--|
| Applicant's/Registrant's Name, Address, and Telephone Number Copper Development Association 260 Madison Avenue New York, New York 10016 Tel: (202) 828-8967 | EPA Registration Number/File Symbol 82012-3 |
| Active Ingredient(s) and/or representative test compound(s) Copper, metallic (PC Code 22501) | Date September 12, 2014 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, Non-Food | Product Name Antimicrobial Copper Alloys Group III |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

| | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| | | |
|---------------|-----------------------------------|--|
| Signature | Date September 12, 2014 | Typed or Printed Name and Title Micah T. Reynolds, Regulatory Consultant |
|---------------|-----------------------------------|--|




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DATA MATRIX

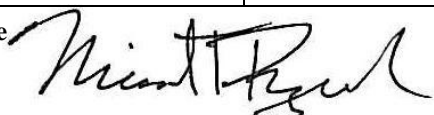
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|--|--|----------------------|---|--------|---------------------------------------|
| Date September 12, 2014 | | | EPA Reg. No./File Symbol 82012-3 | | Page 1 of 6 |
| Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | | Product Antimicrobial Copper Alloys Group III | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| PRODUCT CHEMISTRY: | | | | | |
| 830.1550 | Product Identity and Composition | 46999301 47259201 | Copper Development Association | OWN | |
| 830.1600 | Description of Materials Used to Produce the Product | 46999301 | Copper Development Association | OWN | |
| 830.1620 | Description of Production Process | 46999301 | Copper Development Association | OWN | |
| 830.1650 | Description of Formulation Process | 46999301 | Copper Development Association | OWN | |
| 830.1670 | Discussion of Formation of Impurities | 46999301 | Copper Development Association | OWN | |
| 830.1700 | Preliminary Analysis | 46999301 47160802 | Copper Development Association | OWN | |
| 830.1750 | Certification of Limits | 49445901 | Copper Development Association | OWN | |
| 830.1800 | Enforcement Analytical Methods | 46999301 | Copper Development Association | OWN | |
| 830.1900 | Submittal of Samples | 46999301 | Copper Development Association | | Upon Request |
| 830.6302 | Color | 47160801 | Copper Development Association | OWN | |
| 830.6303 | Physical State | 47160801 | Copper Development Association | OWN | |
| Signature  | | | Name and Title Micah T. Reynolds, Regulatory Consultant to Copper Development Association, Inc. | | Date September 12, 2014 |



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|--|---|-------------|--|--------------------|-----------------------------------|
| Date September 12, 2014 | | | EPA Reg. No./File Symbol 82012-3 | Page 2 of 6 | |
| Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | | Product Antimicrobial Copper Alloys Group III | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| PRODUCT CHEMISTRY (Cont.): | | | | | |
| 830.6304 | Odor | 47160801 | Copper Development Association | OWN | |
| 830.6314 | Oxidizing or Reducing Action | 47160801 | Copper Development Association | OWN | |
| 830.6315 | Flammability | 47160801 | Copper Development Association | OWN | |
| 830.6316 | Explosibility | 47160801 | Copper Development Association | OWN | |
| 830.6317 | Storage Stability | 47160801 | Copper Development Association | OWN | |
| 830.6319 | Miscibility | 47160801 | Copper Development Association | OWN | |
| 830.6320 | Corrosion Characteristics | 47160801 | Copper Development Association | OWN | |
| 830.6321 | Dielectric Breakdown Voltage | 47160801 | Copper Development Association | OWN | |
| 830.7000 | pH | 47160801 | Copper Development Association | OWN | |
| 830.7100 | Viscosity | 47160801 | Copper Development Association | OWN | |
| 830.7300 | Density, Bulk Density or Specific Gravity | 47160801 | Copper Development Association | OWN | |
| Signature  | | | Name and Title Micah T. Reynolds, Regulatory Consultant to Copper Development Association, Inc. | | Date September 12, 2014 |

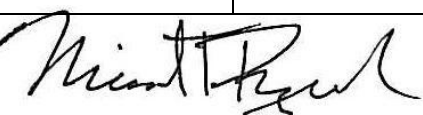
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|--|----------------------------------|-------------|---|--------------------|---------------------------------------|
| Date September 12, 2014 | | | EPA Reg. No./File Symbol 82012-3 | Page 3 of 6 | |
| Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | | Product Antimicrobial Copper Alloys Group III | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| TOXICOLOGY: | | | | | |
| 870.1100 | Acute Oral Toxicity: Rat | 46999302 | Copper Development Association | OWN | |
| 870.1200 | Acute Dermal Toxicity: Rat | 46999302 | Copper Development Association | OWN | |
| 870.1300 | Acute Inhalation Toxicity: Rat | 46999302 | Copper Development Association | OWN | |
| 870.2400 | Primary Eye Irritation: Rabbit | 46999302 | Copper Development Association | OWN | |
| 870.2500 | Primary Dermal Irritation | 46999302 | Copper Development Association | OWN | |
| 870.2600 | Dermal Sensitization | 46999302 | Copper Development Association | OWN | |
| 870.3100 | 90-Day Oral Toxicity | 46999302 | Copper Development Association | OWN | |
| 870.3150 | 90-Day Oral Toxicity – Nonrodent | 46999302 | Copper Development Association | OWN | |
| 870.3250 | 90-Day Dermal Toxicity | 46999302 | Copper Development Association | OWN | |
| 870.3700 | Teratology – Rats | 46999302 | Copper Development Association | OWN | |
| 870.3700 | Teratology – Rabbits | 46999302 | Copper Development Association | OWN | |
| Signature  | | | Name and Title Micah T. Reynolds, Regulatory Consultant to Copper Development Association, Inc. | | Date September 12, 2014 |

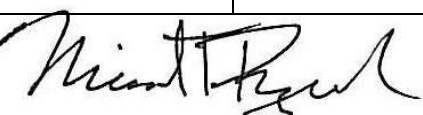


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| Date | September 12, 2014 | EPA Reg. No./File Symbol | 82012-3 | Page 4 of 6 | |
| Applicant's/Registrant's Name & Address: | | Product | | | |
| Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | Antimicrobial Copper Alloys Group III | | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| TOXICOLOGY (Cont.): | | | | | |
| 870.3800 | Reproduction and Fertility Effects | 46999302 | Copper Development Association | OWN | |
| 870.4100 | Chronic Oral/Feeding Study | 46999302 | Copper Development Association | OWN | |
| 870.5100 | Bacterial Reverse Mutation (Ames) Test | 46999302 | Copper Development Association | OWN | |
| 870 Genotoxicity Series | Other Mutagenicity | 46999302 | Copper Development Association | OWN | |
| 870.7485 | Metabolism and Pharmacokinetics - Rat | 46999302 | Copper Development Association | OWN | |
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| | | | | | |
| | | | | | |
| Signature  | | | Name and Title | | Date |
| | | | Micah T. Reynolds, Regulatory Consultant to Copper Development Association, Inc. | | September 12, 2014 |



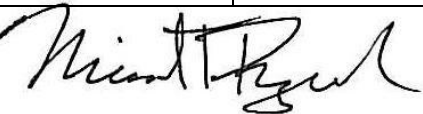
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| Date | September 12, 2014 | EPA Reg. No./File Symbol | 82012-3 | Page 5 of 6 | |
| Applicant's/Registrant's Name & Address: | | Product | | | |
| Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | Antimicrobial Copper Alloys Group III | | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| EFFICACY: | | | | | |
| 810.2300 | Hard Surface Sanitizer Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048) | 46999306 46999310 46999312 | Copper Development Association | OWN | |
| 810.2300 | Hard Surface Sanitizer Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442) | 46999307 | Copper Development Association | OWN | |
| 810.2300 | Hard Surface Sanitizer Assay: <i>VRE. Faecalis</i> (ATCC 51575) | 47859501 | Copper Development Association | OWN | |
| 810.2300 | Residual Self-Sanitizer Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048) | 46999308 | Copper Development Association | OWN | |
| 810.2300 | Residual Self-Sanitizer Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442) | 46999309 | Copper Development Association | OWN | |
| 810.2300 | Residual Self-Surface Sanitizer Assay: <i>VRE. Faecalis</i> (ATCC 51575) | 47859502 | Copper Development Association | OWN | |
| | | | | | |
| Signature  | | | Name and Title Micah T. Reynolds, Regulatory Consultant to Copper Development Association, Inc. | | Date September 12, 2014 |



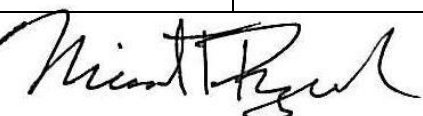
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DATA MATRIX

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|---|---|---------------------------------------|--|-------------|-------------------------------|
| Date | September 12, 2014 | EPA Reg. No./File Symbol | 82012-3 | Page 6 of 6 | |
| Applicant's/Registrant's Name & Address: | | Product | | | |
| Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | Antimicrobial Copper Alloys Group III | | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| EFFICACY (Cont.): | | | | | |
| 810.2300 | Repeat Challenge Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048) | 46999304 46999311 46999313 | Copper Development Association | OWN | |
| 810.2300 | Repeat Challenge Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442) | 46999305 | Copper Development Association | OWN | |
| 810.2300 | Repeat Challenge Assay: <i>VRE. Faecalis</i> (ATCC 51575) | 47859503 | Copper Development Association | OWN | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Signature  | | | Name and Title Micah T. Reynolds, Regulatory Consultant to Copper Development Association, Inc. | | Date September 12, 2014 |



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| Date | September 12, 2014 | EPA Reg. No./File Symbol | 82012-3 | Page | 1 of 6 |
| Applicant's/Registrant's Name & Address: | Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | Product | Antimicrobial Copper Alloys Group III | | |

Ingredient **Copper as elemental (PC Code 22501)**

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|----------------------|-------------|--------------------------------|--------|--------------|
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| | | | Copper Development Association | OWN | |
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| Signature |  | Name and Title | Micah T. Reynolds, Regulatory Consultant to Copper Development Association, Inc. | Date | September 12, 2014 |
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| Date September 12, 2014 | EPA Reg. No./File Symbol 82012-3 | Page 2 of 6 |
| Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | Product Antimicrobial Copper Alloys Group III | |

Ingredient **Copper as elemental (PC Code 22501)**

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
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| Signature  | Name and Title Micah T. Reynolds, Regulatory Consultant to Copper Development Association, Inc. | Date September 12, 2014 |
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| Date September 12, 2014 | | | EPA Reg. No./File Symbol 82012-3 | | Page 3 of 6 |
| Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | | Product Antimicrobial Copper Alloys Group III | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
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| Date | September 12, 2014 | EPA Reg. No./File Symbol | 82012-3 | Page 4 of 6 | |
| Applicant's/Registrant's Name & Address: | | Product | | | |
| Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | Antimicrobial Copper Alloys Group III | | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
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| Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016 | | | Product Antimicrobial Copper Alloys Group III | | |
| Ingredient Copper as elemental (PC Code 22501) | | | | | |
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| Ingredient Copper as elemental (PC Code 22501) | | | | | |
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